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Docket No.: 01946/100A483-US8
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Sam J. Milstein, et al.

Application No.: 09/760,307

Confirmation No.: 8759

Filed: January 11, 2001

Art Unit: 1615

For: ACTIVE AGENT TRANSPORT SYSTEMS

Examiner: L. S. Channavajjala

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the reference listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed after the first Office Action on the merits, and is accompanied by the fee set forth in 1.17(p).

A full translation or abstract of the non-English language documents are enclosed. Please note that the abstract for FR 4,446 is citation no. 52, "Francia Farmaceutica γ -(o-Hydroxybenzamido)-Butyric Acid", Chem. Abstracts, vol. 10, 114838e (1969).

A copy of each document on this PTO/SB/08 is attached.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: July 16, 2004

Respectfully submitted,

By 

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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete If Known	
		Application Number	09/760,307-Conf. #8759		
		Filing Date	January 11, 2001		
		First Named Inventor	Sam J. Milstein		
		Art Unit	1615		
		Examiner Name	L. S. Channavajjala		
		Attorney Docket Number	01946/100A483-US8		
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U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (# known)			
	1	US-6,221,367-B1	04-24-2001	Milstein et al.	
	2	US-6,242,495-B1	06-05-2001	Leone-Bay, et al.	
	3	US-6,245,359-B1	06-12-2001	Milstein, et al.	
	4	US-6,313,088-B1	11-06-2001	Leone-Bay et al.	
	5	US-6,344,213-B1	02-05-2002	Leone-Bay et al.	
	6	US-6,346,242-B1	02-12-2002	Leone-Bay et al.	
	7	US-6,348,207-B1	02-19-2002	Milstein et al.	
	8	US-6,358,504-B1	03-19-2002	Leone-Bay et al.	
	9	US-6,384,278-B1	05-07-2002	Tang, et al.	
	10	US-6,391,303-B1	05-21-2002	Haas et al.	
	11	US-6,399,798-B1	06-04-2002	Gschneider et al.	
	12	US-6,428,780-B1	08-06-2002	Leone-Bay et al.	
	13	US-6,440,929-B1	08-27-2002	Milstein et al.	
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	15	US-6,525,020-B1	02-25-2003	Leone-Bay et al.	
	16	US-2002-0001591-A1	01-03-2002	Santiago et al.	
	17	US-6,610,329-B1	08-26-2003	Santiago et al.	
	18	US-6,623,791-B1	09-23-2003	Leone-Bay et al.	
	19	US-6,642,411-B1	11-04-2003	Leone-Bay et al.	
	20	US-6,646,162-B1	11-11-2003	Tang et al.	
	21	US-2002-0120009-A1	08-29-2002	Leone-Bay et al.	
	22	US-6,663,887-B1	12-16-2003	Leone-Bay et al.	
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	25	US-6,699,467-B1	03-02-2004	Leone-Bay et al.	
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ³ -Number ⁴ -Kind Code ⁵ (# known)				
	27	WO-01/32130-A1	05-10-2001	Emisphere Technologies, Inc.		
	28	WO-01/32596-A1	05-10-2001	Emisphere Technologies, Inc.		
	29	WO-01/44199-A1	06-21-2001	Emisphere Technologies, Inc.		
	30	WO-01/51454-A1	07-19-2001	Emisphere Technologies, Inc.		
	31	WO-01/70219-A1	09-27-2001	Emisphere Technologies, Inc.		
	32	WO-01/92206-A1	12-06-2001	Emisphere Technologies, Inc.		
	33	WO-02/069937-A1	09-12-2002	Emisphere Technologies, Inc.		
	34	WO-02/070438-A1	09-12-2002	Emisphere Technologies, Inc.		
	35	WO-02/100338-A1	12-19-2002	Emisphere Technologies, Inc.		
	36	WO-02/19969-A1	03-14-2002	Emisphere Technologies, Inc.		
	37	WO-03/002000-A1	04-03-2003	Emisphere Technologies, Inc.		
	38	WO-03/045306-A1	06-05-2003	Emisphere Technologies, Inc.		
	39	WO-03/057170-A1	07-17-2003	Emisphere Technologies, Inc.		
	40	WO-03/057650-A1	07-17-2003	Emisphere Technologies, Inc.		
	41	EP-0 576 941-A1	01-05-1994	Nissin Flour Milling Co., Ltd.		
	42	FR-4446-A1	09-26-1966	Francia Farmaceutica, S.r.l.		

Examiner Signature	Date Considered	
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
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				Attorney Docket Number	01946/100A483-US8
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	43	WO-97/47270-A1	12-18-1997	Arad, Dorit	
	44	WO-99/29705-A1	06-17-1999	Glycomed Inc.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	45	Leone-Bay, A., "N-Acylated alpha-amino acids as novel oral delivery agents for proteins"; <i>Journal of Medicinal Chemistry</i> vol 38, 4263-4269 (1995).	
	46	Leone-Bay, A. "Microsphere Formation in a Series of Derivatized Alpha-Amino Acids: Properties, Molecular Modeling, and Oral Delivery of Salmon Calcitonin"; <i>Journal of Medicinal Chemistry</i> vol 38, 4257-4262 (1995).	
	47	Ho Koc-Kan, et al. "A Practical Synthesis of -aminoalkanoic acid derivatives form Cycloalkanones" <i>Synthetic Communication</i> , vol. 26, no. 14: 2641-2649 (1996).	
	48	Leone-Bay, A., "4-(4-Salicyloylaminophenyl)butyric Acid as a Novel Oral Delivery Agent for Recombinant Human Growth Hormone" <i>Medi 006</i> , Presented at the American Chemical Society, (March 1996) New Orleans, LA.	
	49	Leone-Bay, A., et al. "The evolution of an oral heparin dosing solution" <i>Drugs of the Future</i> vol 22(8) 885-891 (1997).	
	50	Ho Koc-Kan, et al. "Solution Phase Preparation of Highly Pure Amide Mixtures Via In-Situ Chlorotrimethylsilane Protection and Activation" <i>Synthetic Communication</i> , vol. 27, no. 5: 883-895 (1997).	
	51	Leone-Bay, A. "Acylated non-alpha-amino acids as novel agents for the oral delivery of heparin sodium, USP" <i>Journal of Controlled Release</i> 50: 41-49 (1998).	
	52	Francia Farmaceutica "γ-(o-Hydroxybenzamido)-Butyric Acid" <i>Chem Abstracts</i> Vol. 10 114838e (1969).	
	53	Picciola, G., "Sintesi Di Acidi Chinazolinonici E Benzossazinonici E Studio Delle Loro Proprieta Antinfiammatorie" <i>IT, Il Farmaco, Ed. Sc.</i> vol 31, no. 9 pgs 655-664 (1976).	
	54	Picciola, G., "Synthesis Of Quinazolinone And Benzoxazainone Acids And Study Of Their Anti-Inflammatory Properties" <i>IT, Il Farmaco, Ed. Sc.</i> vol 31, no. 9 pgs 655-664 - English Translation (1976).	
	55	Picciola, G., "Synthesis Of Quinazolinone And Benzoxazainone Acids And Study Of Their Anti-Inflammatory Properties" <i>Chem Abstract</i> 86:5402t (1977).	
	56	Johansen, Marianne, et al. "Pro-Drugs As Drug Delivery Systems XIII. Kinetics Of Decomposition. Of N-Mannich Bases Of Salicylamide And Assessment Of Their Suitability As Possible Prodrugs For Amines" <i>Int. J. Pharm.</i> (1980), 7(2): 119-27 (1980).	
	57	Brown, G. et al., "Receptor Binding Sites Of Hypoglycemic Sulfonylureas And Related(Acylamino)AlkylBenzoic Acids" <i>J Med Chem</i> 27, 79-81 (1984).	
	58	Amino Yusuke, et al. "Phenylalanine Derivatives Enhancing Intestinal Absorption of Insulin in Mice" <i>Chem Pharm Bull</i> 36 pgs 4426-4434 (1988).	
	59	Frangiano, F., et al., "Synthesis, Stability And Anticonvulsant Activity Of Two New GABA Prodrugs" <i>Pharmazie</i> 52(4): 272-276 (1997).	

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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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